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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,013	10/25/2000	Vincent P. Stanton JR.	030586.0015.UTIL	4545
26161	7590	02/10/2005	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			MYERS, CARLA J	
			ART UNIT	PAPER NUMBER
			1634	
DATE MAILED: 02/10/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/697,013

Applicant(s)

STANTON, VINCENT P.

Examiner

Carla Myers

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 59 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 60 is/are allowed.
- 6) ☒ Claim(s) 59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 3, 2005 has been entered.

Claims 59 and 60 are pending; claims 1-58 have been canceled. All grounds of rejection not reiterated herein are hereby withdrawn.

In particular, the previous grounds of rejection under 35 U.S.C. 101 and 112 are withdrawn in view of Applicant's amendments to the claims to limit the claims to methods which identify the nucleotide present at each of the positions of 16747, 17030, 17785, 19311 and 23707 of the ApoE gene of SEQ ID NO: 5. As set forth on pages 76-77 of the specification, "the haplotype GCAGC in row 1 identifies the alleles designated E3 by the classic ApoE test; and GCAAC (sic) in row 3, specify the alleles designated E4 by the classic ApoE test; and GCAGA, in row 4, identifies the alleles designated E2 by the classic ApoE test" (see Table 5). Accordingly, the specification teaches that the haplotype of alleles 16747, 17030, 17785, 19311 and 23707 of the ApoE gene can be used to distinguish between the ApoE2, ApoE3 and ApoE4 genotypes/phenotypes.

Specification

2. The disclosure is objected to because of the following informalities:

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A. The specification remains objected to because the assigned SEQ ID NOs have not been used to identify each sequence listed, as required under 37 CFR §1.821(d). In particular, the sequence set forth in Table 2 should be accompanied by the appropriate sequence identifier (i.e. SEQ ID NO: 5). Additionally, the description of figures 34 and 35 should include the sequence identifier for the sequences set forth in these figures or the figures themselves should be amended to include the sequence identifiers.

B. In the specification at page 76, it is stated that Table 5 indicates that the "GCAGA, in row 3, specify the alleles designed E4 by the classic ApoE test." However, Table 5 at row 3 indicates that the GCAAC haplotype is indicative of the E4 genotype/phenotype (while the GCAGA haplotype of row 4 is indicative of the E2 genotype/phenotype). Accordingly, the specification at page 76, line 24, should be amended to refer to the "GCAAC" haplotype in place of the "GCAGA", haplotype.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 59 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 59 is indefinite. The claim is drawn to a method for evaluating the haplotype of an allele of the ApoE gene. However, the claim recites only the step of

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identifying the nucleotide present at positions 19311, 23707, 16747, 170303 and 17785.

The claim does not clarify how identifying the stated nucleotides results in the evaluation of a haplotype. Thereby, it is unclear as to whether the method is one which evaluates a haplotype or one which requires only determining the nucleotide present at 19311, 23707, 16747, 170303 and 17785. In view of the fact that the claims do not provide a clear nexus between the preamble and the process steps, it is also unclear as to what is considered to be encompassed by evaluating. For instance, it is unclear as to whether "evaluating" refers to detecting the presence of a particular haplotype or if this refers to analyzing the haplotype based on some other unstated property/characteristic – e.g., the frequency of the haplotype, an association between the haplotype and disease. Appropriate correction of the claim is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 59 is rejected under 35 U.S.C. 102(b) as being anticipated by Freitas (DNA Seq. 1998. 9(2): 89-100).

Freitas teaches a method for sequencing the ApoE gene. The ApoE gene sequenced in the method of Freitas is identical to the present ApoE gene of SEQ ID NO: 5 and includes nucleotide positions 19311, 23707, 16747, 170303 and 17785.

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Thereby, the method of Freitas is one which identifies the nucleotide present at nucleotide positions 19311, 23707, 16747, 170303 and 17785.

It is noted that claim 59 is drawn to a "method for evaluating the haplotype of an allele of ApoE." However, this claim recites only a step of identifying the nucleotide present at ApoE nucleotide positions 19311, 23707, 16747, 170303 and 17785.

Thereby, claim 59 as broadly written is considered to encompass general methods of sequencing the ApoE gene since the recitation in the preamble of "method for evaluating the haplotype of an allele of ApoE" does not result in a manipulative difference in the method steps when compared to the prior art disclosure. Because the method steps recited in the claims (i.e., identifying the nucleotide present at nucleotide positions 19311, 23707, 16747, 170303 and 17785) are the same as those set forth by Freitas, the claimed methods are anticipated by the disclosure of Freitas.

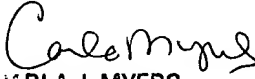
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571)-272-0745.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
February 2, 2005


CARLA J. MYERS
PRIMARY EXAMINER